

Attorney docket No. TIS-104

Inventors: BINDER, S., & TSENG, S.C.G.

STW

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

Applicants: BINDER, S., & TSENG, S.C.G.

Group: 1651

Application No.: 10/530,164 ✓

Examiner:

Filing/371(c) date: April 4, 2005

Docket No.: TIS-104

For: RETINAL PIGMENT EPITHELIAL CELL CULTURES ON
AMNIOTIC MEMBRANE AND TRANSPLANTATION

DATE OF DEPOSIT: MARCH 16, 2006

I hereby certify that the correspondence attached hereto is being deposited with the United States Postal Service with sufficient postage as First Class Mail on the date indicated above in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Enclosed:

1. Return Receipt Postcard (1);
2. Certificate of Mailing by First Class Mail (1 page);
3. Information Disclosure Statement and Citation (5 pgs.);
4. Copy of International Search Report, Notification of Transmittal, and Cover page of WO 2004/033635 A3 (5 pgs); and
5. 23 References (251 -total pgs).

Jacqueline M. Arendt

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Patent Application
Docket No. TIS-104

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Binder, S. & Tseng, S.C.G.

Group Art Unit: 1651

Application No.: 10/530,164

Examiner:

U.S. National Phase of PCT/US03/31464

Filing/371 (c) Date: April 4, 2005

Title: RETINAL PIGMENT EPITHELIAL CELL
CULTURES ON AMNIOTIC MEMBRANE AND
TRANSPLANTATION

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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on March 16, 2006

Jacqueline M. Arendt
Jacqueline M. Arendt

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is an equivalent of form PTO SB/08a (1449) :
- ☒ Copies of the cited references (numbered 8-31) are enclosed.
- ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☒ The listed Reference 8 (GB 2110531 A) was cited in the enclosed International Search Report.
- ☐ The "concise explanation" requirement (non-English references) for reference under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.

☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

☐ the enclosed English language abstract of correspondent application.

☒ It is requested that the information disclosed herein be made of record in this application.

☒ Applicants make no representation that a search has been conducted by Applicants. Applicants also make no representation that the information submitted herewith is in fact material to patentability. The subject application is believed patentable over any of the references.

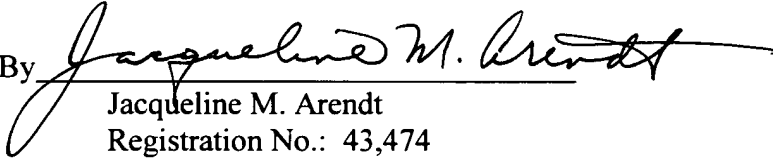
Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☒ No fee is due.

Respectfully submitted,

ARENDR & ASSOCIATES INTELLECTUAL PROPERTY GROUP

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Date: March 14, 2006



INFORMATION DISCLOSURE CITATION

(USE SEVERAL SHEETS IF NECESSARY)

ATTY DOCKET NO.

TIS-104

SERIAL NO.

10/530,164

APPLICANT(S)

SCHEFFER C.G. TSENG, *ET. AL.*

FILING DATE/371 (C) DATE:

APRIL 4, 2005

GROUP

1651

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1.	US 6,152,142	28 Nov. 2000	Tseng, SCG	128	898	20 Feb. 1998
	2.	US 6,326,019 B1	04 Dec. 2001	Tseng, SCG	424	424	25 July 2000
	3.	US 2005/0026279 A1	03 Feb 2005	Tseng, SCG & Espana, E. M.	435	378	28 April 2004
	4.	US 2002/0039788 A1	04 Apr 2002	Isseroff, R. R. & Schwab, I.R.	435	366	28 Feb 2001
	5.	US 2003/0208266 A1	06 Nov 2003	Tsai, R.	623	005	13 Dec 2002
	6.	US 2004/0009590 A1	15 Jan 2004	Tan, D., <i>et. al.</i>	435	366	31 Mar 2003
	7.	US 6,045,791	04 Apr 2000	Liu, Y.	424	93.7	19 May 1995

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
							NO	YES	ABSTRACT
	8.	GB 2110531 A	22 Jun 1983	U.K.	A61K35	50			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	9.	Copy of International Search Report dated 25-Jan-2005, for PCT/US03/31464 (3 sheets), Notification of Transmittal (1 pg.), Cover sheet of WO 2004/033635 A3.
	10.	Binder, S., <i>et al.</i> , "Transplantation of Autologous Retinal Pigment Epithelium in Eyes With Foveal Neovascularization Resulting From Age-Related Macular Degeneration: A Pilot Study," <i>Am J Ophthalmol</i> , 133(2): 215-25 (2002).
	11.	Phillips, S.J., <i>et al.</i> , "Autologous Transplantation of Retinal Pigment Epithelium After Mechanical Debridement of Bruch's Membrane," <i>Invest Ophthalmol Vis Sci.</i> , In Press 1-11 (2002).
	12.	Pfeffer, B.A., "Improved Methodology for Cell Culture of Human and Monkey Retinal Pigment Epithelium," <i>Prog. Retin. Eye Res.</i> , Chapter10: 251-91 (1991).
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	14.	Hu, J., Bok, D., "A cell culture medium that supports the differentiation of human retinal epithelium into functionally polarized monolayers," <i>Molecular Vision</i> , 7:14-19 (2000).
	15.	Dutt, K., <i>et al.</i> , " Extracellular matrix mediated growth and differentiation in human pigment epithelial cell line 0041," <i>Current Eye Research</i> , 10 (12): 1089-100 (1991).
	16.	Lu, L., <i>et al.</i> , "Retinal pigment epithelium engineering using synthetic biodegradable polymers," <i>Biomaterials</i> , 22: 3345-55 (2001).

INFORMATION DISCLOSURE CITATION (USE SEVERAL SHEETS IF NECESSARY)	ATTY DOCKET NO.	SERIAL NO.
	TIS-104	10,530,164
	APPLICANT(S) TSENG ET AL	
	FILING DATE/ 371 (C) DATE:	GROUP
	APRIL 4, 2005	1651

17.	Kim, J.C., Tseng, S.C.G., "Transplantation of Preserved Human Amniotic Membrane for Surface Reconstruction in Severely Damaged Rabbit Corneas," <i>Cornea</i> , 14:473-84 (1995).
18.	Tezel, T.H., et al., "Fate of Human Retinal Pigment Epithelial Cells Seeded onto Layers of Human Bruch's Membrane," <i>Invest. Ophthalmol. Vis. Sci.</i> , 40:467-76 (1999).
19.	Dua, H.S., Azuara-Blanco, A., "Amniotic membrane transplantation," <i>Br.J.Ophthalmol</i> , 83:748-52 (1999).
20.	Grueterich, M., Espana, E., Tseng, S.C.G., "Connexin 43 Expression and Proliferation of Human Limbal Epithelium on Intact and Denuded Amniotic Membrane," <i>Invest Ophthalmol Vis.Sci.</i> , 43:63-71 (2002).
21.	Meller, D., Tseng, S.C.G., "Conjunctival Epithelial Cell Differentiation on Amniotic Membrane," <i>Invest. Ophthalmol. Vis. Sci.</i> , 40:878-86 (1999).
22.	Lu, L., et al., "Retinal pigment epithelium cell culture on thin biodegradable poly(DL-lactic-co-glycolic acid) films," <i>J Biomater. Sci. Polymer Edn.</i> , 9(11):1187-205 (1998).
23.	Singh, S., et al., "Natural and artificial substrates for retinal pigment epithelial monolayer transplantation," <i>Biomaterials</i> , 22:3337-343 (2001).
24.	DelPriore, L., Tezel, T., "Reattachment Rate of Human Retinal Pigment Epithelium to Layers of Human Bruch's Membrane," <i>Arch Ophthalmol</i> , 116: 335-41 (1998).
25.	Koizumi, N., et al., "Cultivation of Corneal Epithelial Cells on Intact and Denuded Human Amniotic Membrane," <i>Invest. Ophthalmol. Vis. Sci.</i> , 41(9):2506-513 (2000 Aug).
26.	Koizumi, N., et al., "Amniotic Membrane as a Substrate for Cultivating Limbal Corneal Epithelial Cells for Autologous Transplantation in Rabbits," <i>Cornea</i> , 19(1):65-71 (2000).
27.	Koizumi, N., et al., "An Evaluation of Cultivated Corneal Limbal Epithelial Cells, Using Cell-Suspension Culture," <i>Invest. Ophthalmol. Vis. Sci.</i> , 43 (7): 2114-121 (2002 July).
28.	Gruetrich, M., Tseng, S.C.G., "Human Limbal Progenitor Cells Expanded on Intact Amniotic Membrane <i>Ex Vivo</i> ," <i>Arch Ophthalmol</i> , 120:783-90 (2002 June).
29.	Espana, E., et al., "Human Keratocytes Cultured on Amniotic Membrane Stroma Preserve Morphology and Express Keratocan," <i>Invest. Ophthalmol. Vis. Sci.</i> , 44(12):5136-141 (2003 December).
30.	Koh, S.-W., "VIP Enhances the Differentiation of Retinal Pigment Epithelium in Culture: from cAMP and pp60 ^{c-src} to Melanogenesis and Development of Fluid Transport Capacity," <i>Progress in Retinal and Eye Research</i> , 19(6):669-88 (2000).
31.	Albert, D.M., et al., "In Vitro Growth of Pure Cultures of Retinal Pigment Epithelium," <i>Arch Ophthalmol</i> , 88: 63-69 (1972).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial here if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Please include copy of this form with next communication to applicant.	